APR 1 8 2001

H&C Medical Devices FDA DOCUMENT NUMBER: K010822

5. Summary of Safety and Effectiveness

AB CARDIETTE Start 200 HV

5.1 Date of application: 03/19/2001

5.2 Applicant's name and address: H&C Medical Devices spa
Via Pisa 250
20099 Sesto San Giovanni
(Milan) ITALY

5.3 Contact person: Mr. Attilio Castelli
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5.4 Device Trade Name
AB CARDIETTE Start 200 HV

5.5 Device Common Name
ECG Interpretive Electrocardiograph

5.6 Device Classification Name
CFR 870.2340 Electrocardiograph Class II 74 DPS

5.7 Unmodified (Predicate) Device
The legally marketed device which has been modified is:

Manufacturer Name	Applicant Name	Predicate Device	510(k) Number
Elettronica Trentina spa	H&C Medical Devices spa	AB CARDIETTE Daedalus View base and Hes	**K002074**

The safety features of the AB CARDIETTE Start 200 HV are identical to those of the predicate Daedalus View. The performances of AB CARDIETTE Start 200 HV are basically similar to the predicate Daedalus View and are summarized in table 5.7.1. The Interpretation Program implemented in AB CARDIETTE Start 200 HV is identical to the one implemented in the predicate Daedalus View Hes.
Intended use of AB CARDIETTE Start 200 HV is identical to that of AB CARDIETTE Daedalus View base and Hes.

Summary of Safety and Effectiveness (con't)

Table 5.7.1

Parameter	AB CARDIETTE Start 200 HV	AB CARDIETTE DAEDALUS VIEW Base and Hes
RECORDER		
Input dynamic range	+/-300mV @ DC +/- 6.4 mV within the bandpass	+/-300mV @ DC +/- 25 mV within the bandpass
Frequency response	0.05 – 150 Hz (-3dB)	0.05 – 150 Hz (-3dB)
A/D conversion	12 bits	14 bits
Leads	12 Standard	12 Standard / 12 Cabrera
Sensitivity	5 10 20 mm/mV +/-5%	1.25 2.5 5 10 20 40 mm/mV +/-5%
Writing system	Thermal head 210 mm 8 dots/mm	Thermal head 108 mm 8 dots/mm
Printed channels	3/4/6/12	3/4/6/12
Paper speed	5 mm/s +/-10% 25 50mm/s +/-5%	1.25 2.5 5 10 12.5 mm/s +/-10% 25 50mm/s +/-5%
Thermal paper	DOTCARD 210 mm	DOTCARD 210 mm
Mode of operation	Manual and Automatic recording	Manual, Manual delayed and Automatic recording
Input/output	RS 232 standard digital port	RS 232 standard digital port
DISPLAY		
Size	128 x 64 pixels	VGA 640 x 480 pixels
N° of displayed channels	1	3 / 6
Traces speed	35 mm/s	1.25 2.5 5 10 12.5 25 50 mm/s
Sensitivity	5 10 20 mm/mV	1.25 2.5 5 10 20 40 mm/mV

5.8 Device description

AB CARDIETTE Start 200 HV is an electrocardiograph providing the following characteristics:

- Mains and internal battery operation
- Manual acquisition of the 12 Standard Leads
- Simultaneous acquisition of the 12 Standard Leads
- Storage of 10 seconds of acquired ecg signal
- Ecg printout of either 3, 4, 6 or 12 leads per page
- Copy function of the stored ecg
- High resolution digital thermal printer
- Digital filters for AC interference suppression, base-line drift and muscolar tremour suppression
- Grid printout on white paper

Summary of Safety and Effectiveness (con't)

- Interpretation Program Hannover Ecg System (HES) providing the following additional informations:
  - Representatives Templates of each lead including markers on fiducial points
  - Summary of mean measurements
  - Summary of measurements performed on each lead
  - Rythm Analysys Statements
  - Rythm graphical representation
  - Signal noise detection and information
  - Specific findings on QRS complex
  - Conduction statements
  - QRS T Diagnostic Statements
  - Summary of measurements performed on each lead

- 128 x 64 pixels graphic LCD display for user interface and display of EKG signals
- Patient input data for Interpretation, identification and filing purposes
- Possibility to send acquisition data to a Personal Computer or Workstation via RS232 interface

5.9 Intended use

AB CARDIETTE Start 200 HV is an electrocardiograph characterized as basic standard electrocardiograph with program for automated ecg analysis and an LCD graphic display.

Intended use is equivalent to the intended use of the predicate Daedalus View.
More specifically:
The equipment is intended for use in routine ecg recording in physician practice and/or hospital. The electrical heart activity is detected by means of two or more electrocardiograph electrodes and can be visualized on a digital display and recorded on thermal paper.

Intended use for non interpretive applications covers the full range of patient population with no limitiations with respect to age, sex and race of the patient.

The interpretation program is intended to provide a diagnostic support to the physician for the ecg evaluation on rythm and morphology.

Summary of Safety and Effectiveness (con't)

5.10 Comparison of technological characteristics
AB CARDIETTE Start 200 HV electrocardiograph is based on the same technological characteristics of the predicate device AB CARDIETTE Daedalus View base and Hes.

5.11 Non clinical tests used for Substantial Equivalence Determination
Full safety tests according to EN60601-1 and IEC 601-2 25 have been performed on AB CARDIETTE Start 200 HV. Tests have shown full compliance with these standards.
The equipment have been subject to Electromagnetic Compatibility testing procedures according to EN60601-1-2 standard. Tests have shown full compliance with this standard.
The correct implementation of the measurements and interpretation program has also been tested and validated.
The measurements and interpretation program has not been changed. It has been intensively tested and validated by the developer Medizinische Hochschule Hannover. Test results have been published on the New England Journal of Medecine 325:1767-1773 December 19, 1991 under the title:
The Diagnostic Performance of Computer Programs for the Interpretation of Electrocardiograms.
The results shown in this study have demonstrated the quality and accuracy of the HES program with respect to other commercially availabe programs.
Moreover, the equipment is marketed worldwide since 1998 under the name CARDIETTE Start 200 HV.
No adverse working conditions have been claimed and filed up to date.
Both equipments are CE marked according to 93/42/CEE Medical Device Directive.

5.12 Risk Analysis
Comparative risk analysis has been performed with respect to the umodified (predicate) device demonstrating that all means adopted for risk reduction were identical to those adopted for the umodified equipment. The safety and the risk related to the use of the modified equipment are identical to the unmodified equipment

5.13 Conclusions
Based on the above, H&C Medical Devices belives that AB CARDIETTE Start 200 HV is substantially equivalent to AB CARDIETTE Daedalus View base and Hes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2001

Mr. Attilio Castelli
H&C Medical Devices spa
Via Pisa 250
20099 Sesto San Giovanni (Milano)
ITALY

Re: K010822
Trade Name: AB CARDIETTE Start 200 HV
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: March 19, 2001
Received: March 19, 2001

Dear Mr. Castelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Device Name: AB CARDIETTE Start 200 HV.

Indication for Use:

AB CARDIETTE Start 200 HV is an electrocardiograph recorder provided with a program for automated ecg analysis and a small graphic LCD display.

The equipment is intended for use in routine ecg recording in physician practice and/or hospital. The electrical heart activity is detected by means of two or more electrocardiograph electrodes and can be visualized on a digital display and recorded on thermal paper.

Intended use for non interpretive applications covers the full range of patient population with no limitiations with respect to age, sex and race of the patient.

The interpretation program is intended to provide a diagnostic support to the physician for the ecg evaluation on rythm and morphology.

Interpretation Statements must be overwieved and approved by trained Physician's. Interpretation statements just represent a partial qualitative and quantitative information of the general patient cardiovascular condition: no therapy or drugs can be subministrated based solely on Interpretation statements.

The equipments are intended to be used by trained medical personnel or physician's.

Indication for use of the modified device has not been changed with respect to the predicate device AB CARDIETTE DAEDALUS VIEW base and Hes K002074.

Division of Cardiovascular & Respiratory Devices
510(k) Number K010822

Prescription Use ✓